K081496

JUN 12 2008

GE Healthcare

510(k) Summary of Safety and Effectiveness (in accordance to 21 CFR 807.87(h))

Device Name

Proprietary Device Name:	Discovery XR and XA Diagnostic Imaging Systems
Date prepared:	April 4, 2008

Establishment Name and Registration Number of Submitter

Name:	GE Healthcare 3000 N. Grandview Blvd. Waukesha, WI 53188
Registration Number:	2126677
Corresponding Official:	D. Duersteler GE Healthcare P.O. Box 414 Milwaukee, WI 53201 Phone: 262-312-7029 FAX: 262-312-7144 Email: david.duersteler@med.ge.com

Device Classification

Classification Code:	90 KPS/90 JAK
Panel Identification:	Radiology
Classification Name:	Emission Computed Tomography System/Computed Tomography X-ray System (Per 21CFR 892.1200 and 21CFR 892.1750)
Common Name:	PET/CT Imaging System
Classification Class:	Class II Product
Reason for 510(k) Submission:	Modification to existing device

Device Description

The Discovery XR and XA are integrated multi-slice Computed Tomography and Positron Emission Tomography scanners. They use CT images to correct for non-uniform attenuation of the PET images and integrated CT and PET images to localize emission activity in the patient anatomy. Discovery XR and XA have capabilities for imaging all available PET tracers and CT contrast agents and can provide inherently registered anatomical and functional information via an integrated graphical user interface. Discovery XR and XA can also be used as a stand-alone head and whole body multislice CT diagnostic imaging system.

Identification of Legally Marketed Equivalent Devices

GE Healthcare	Discovery VCT	K050559

General Electric Company
P.O. Box 414
Milwaukee, WI 53201

Comparison with Predicate Device

The GE Discovery XR and XA Systems are the same as the above predicate device in that they combine a CT and PET scanner system to produce head and whole body attenuation corrected PET images and localization of emission activity in patient anatomy by means of integrated PET and CT images. They employ the same basic major components including integrate PET and CT gantris, patient table, operator console for analysis and display, and a power distribution unit. The fundamental technology of detecting photons emitted from the patient as a result of positron emitting PET tracers creating coincidence events that are detected by a scintillator material and photodetector is the same as the predicate device. The GE Discovery XR and XA differ from the Discovery VCT in the design of the PET gantry subsystem acquisition electronics, an additional optional reconstruction mode, specific CT models integrated with the system, and improved user interface.

Indications for Use of Device

The GE Discovery XR and XA Systems are intended for head and whole body attenuation corrected Positron Emission Tomography (PET) imaging and localization of emission activity in patient anatomy by means of integrated PET and CT images.

The Discovery XR and XA are to be used by trained health care professionals for imaging the distribution of radiopharmaceuticals in the body for the assessment of metabolic (molecular) and physiologic functions. This can assist in the evaluation, diagnosis, staging, restaging, and follow up of lesions, disease and organ function such as (but not limited to) cancer, cardiovascular disease, and brain dysfunction. These devices can also assist in radiotherapy planning.

The Discovery XR and XA can also be used as stand-alone head and whole body multislice computed tomography (CT) diagnostic imaging systems.

Conclusion

In the opinion of GE Healthcare, the GE Discovery XR and XA Systems are substantially the same in design, materials, energy sources, and technology, do not introduce new safety concerns, perform as well as currently marketed devices, and are therefore substantially equivalent in terms of safety and effectiveness to the currently marketed Discovery VCT System.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2008

GE Medical Systems. LLC
% Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services
2307 E. Aurora Rd., Unit B7
TWINSBURG OH 44087

Re: K081496
Trade/Device Name: Discovery XR and XA Diagnostic Imaging Systems
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: May 28, 2008
Received: May 29, 2008

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081496
Device Name: Discovery XR and XA Diagnostic Imaging Systems

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The Discovery XR and XA can also be used as stand-alone head and whole body multislice computed tomography (CT) diagnostic imaging systems.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K081496